United States Court of Appeals for the Fifth Circuit

United States Court of Appeals
Fifth Circuit
FILED
October 18, 2021
Lyle W. Cayce
Clerk

No. 20-30793

MATTHEW NAQUIN,

Plaintiff—Appellant,

versus

MEDTRONIC, INCORPORATED,

Defendant—Appellee.

Appeal from the United States District Court
for the Eastern District of Louisiana
USDC No. 2:20-CV-2401

Before DAVIS, ELROD, and OLDHAM, *Circuit Judges*.

PER CURIAM:[*]

Medtronic manufactures, among other things, implantable cardiac defibrillators. In 2016, a surgeon implanted a Medtronic defibrillator into Matthew Naquin's chest. Claiming the defibrillator was defective, Naquin sued Medtronic. The district court dismissed Naquin's claims. We affirm.

[*] Pursuant to 5TH CIRCUIT RULE 47.5, the court has determined that this opinion should not be published and is not precedent except under the limited circumstances set forth in 5TH CIRCUIT RULE 47.5.4.

I.

To mitigate various heart conditions, an unidentified cardiologist recommended that Matthew Naquin use a Medtronic Evera XT VR Implantable Cardiac Defibrillator (the "ICD"). On March 30, 2016, an unidentified surgeon implanted the ICD into Naquin's chest, along with a Medtronic Sprint Quattro Lead (the "lead").[1] The FDA has designated both the ICD and the lead as Class III medical devices, which means, among other things, that both underwent a lengthy FDA premarket approval ("PMA") process before their commercial use. According to Naquin, the ICD shocked him unnecessarily, caused severe pain, and created a burning sensation in his chest. Naquin also claims that the lead was defective and caused the whole device to fail roughly three years after implantation, necessitating surgery to replace the device. The replacement surgery was performed on June 23, 2019, and resulted in a three-month hospitalization.

Naquin sued Medtronic in Louisiana state court, bringing products liability and breach of contract claims. The products liability claim sought damages under the Louisiana Products Liability Act ("LPLA") for defective construction, defective design, failure to warn, and breach of express warranty. *See* LA. REV. STAT. ANN. § 9:2800.54. Naquin also asserted a breach of contract claim, arguing that Medtronic had agreed to provide "reliable 24 hour and 7 day a week service to Matthew Naquin." Naquin alleged that the contract was breached because "Medtronic Inc. and its

[1] In total, Naquin asserts that seven Medtronic products were defective: (1) the ICD; (2) the lead; (3) the Medtronic Reveal LINQ; (4) the Medtronic Reveal Insertable Loop Recorder; (5) the My Carelink Patient Monitor and Software; (6) the "Medtronic and EDevice Inc. Wirex"; and (7) the Vital Sync Virtual Patient Monitoring Platform. The first four products were surgically implanted as part of the ICD system; the final three were used in conjunction with the first four but not surgically implanted. Naquin's particularized allegations of defect and injury only relate to the ICD and the lead.

employees and representative provided bad service to Matthew Naquin." Medtronic also allegedly failed to provide "appropriate qualified staff and professionals for service" to Naquin, and "failed to provide reliable software."[2]

Medtronic filed a motion to dismiss. The district court granted the motion with respect to the products liability claim, finding it preempted by 21 U.S.C. § 360k. That statute expressly preempts state laws which impose "different" or "addition[al]" safety requirements on medical devices subject to the FDA's PMA process. 21 U.S.C. § 360k(a). The devices that Naquin claims harmed him were concededly subject to the PMA process. So, to the extent that the LPLA imposed different or additional requirements on those devices, it was preempted. And Naquin failed to specifically plead any non-preempted "parallel" claim—that is, a claim where LPLA requirements align with FDA requirements and thus avoid preemption.

The district court concluded that Naquin's breach of contract claim was "vague and conclusory" and granted Naquin 14 days from its December 2, 2020, order to "amend his complaint to state with specificity the basis of the legal relationship, who is the obligor, what performance was promised,

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[2] In his opposition to Medtronic's motion to dismiss, Naquin for the first time added a third claim, alleging unfair trade practices under the Louisiana Unfair Trade Practices Act ("LUTPA"), LA. REV. STAT. ANN. §§ 51:1401–30. Because Naquin first raised this claim in his opposition, the district court construed it as a motion for leave to amend. The court then denied the motion as futile because the LUTPA claim was subsumed by the LPLA claim. We agree that the LPLA bars Naquin's LUTPA claim. *See id.* § 9:2800.52 (LPLA provides "the exclusive theories of liability for manufacturers for damage caused by their products"); *see also Touro Infirmary v. Sizeler Architects*, 2004-2210, p. 6 (La. App. 4 Cir. 11/21/06), 947 So. 2d 740, 744 ("Courts have consistently held the LPLA subsumes all possible causes of action, with the exception of a claim in redhibition."); *Pitre v. Yahama Motor Co., Ltd.*, 51 F. Supp. 3d 644, 662 (E.D. La. 2014) ("[F]ederal courts applying Louisiana law have concluded that the LPLA bars plaintiffs from maintaining an action under the LUTPA.").

how the contract was breached, and what damages have resulted." Naquin did not amend his complaint. Instead, he filed a premature notice of appeal on December 11, 2020. Because Naquin had not amended his complaint, the district court entered final judgment on January 14, 2021. Naquin then appealed to us.

II.

Naquin asserts that the district court erred by dismissing his products liability and breach of contract claims. Our review is *de novo*. *Cornerstone Christian Schs. v. Univ. Interscholastic League*, 563 F.3d 127, 133 (5th Cir. 2009).

A.

Naquin asserts that he has adequately pleaded LPLA claims that are not preempted by 21 U.S.C. § 360k. Congress passed that provision as part of the Medical Device Amendments of 1976 ("MDA"), which brought medical devices into the FDA's regulatory ambit. Section 360k(a) provides, in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

In *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), the Supreme Court set forth a framework for determining whether state law claims are preempted by § 360k. First, the court "must determine whether the Federal

Government has established requirements applicable to [the medical device].” *Id.* at 321. Second, if so, the court must determine whether the state law claims are based upon “requirements with respect to the device that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness.” *Id.* at 322 (quotation omitted). If the answer to both questions is yes, then the state law claims are preempted. *See id.* at 321–22.

The first prong of the *Riegel* test is satisfied here. *Riegel* held that if a device has been approved through the PMA process, it satisfies the federal requirements prong. *See id.* at 322 (“Premarket approval . . . imposes ‘requirements’ under the MDA . . . .”); *Bass v. Stryker Corp.*, 669 F.3d 501, 507 (5th Cir. 2012) (“Devices that are approved through PMA procedures automatically satisfy the ‘federal requirements’ prong.” (citing *Riegel*, 552 U.S. at 322)). All of the devices that Naquin alleges were surgically implanted and caused him harm—most notably, the ICD and the lead—are FDA-regulated medical devices that have been approved through the PMA process.

The second prong asks whether the plaintiff’s state law claims impose requirements “that are different from, or in addition to, the federal ones, and that relate to safety and effectiveness.” *Riegel*, 552 U.S. at 322 (quotation omitted). Evaluating Naquin’s LPLA claims would require a jury to decide whether “[t]here existed an alternative design for the product that was capable of preventing [Naquin’s] damage” and whether the safety benefits of that design “outweighed the burden on the manufacturer of adopting such alternative design.” La. Rev. Stat. Ann. § 9:2800.56; *see also id.* § 9:2800.57 (failure-to-warn claim requires that “the manufacturer failed to use reasonable care to provide an adequate warning” of a dangerous characteristic of a product). Because these Louisiana standards relate to safety and effectiveness, they are preempted to the extent they are “different from, or in addition to” federally imposed requirements. 21 U.S.C. § 360k(a); *see Gomez v. St. Jude Medical Daig Div. Inc.*, 442 F.3d 919, 930 (5th Cir. 2006) (finding LPLA

defective-design and failure-to-warn claims for an allegedly defective PMA-approved medical device preempted by § 360k).

But as the Supreme Court explained in *Riegel*, state law claims can avoid preemption if they are "parallel" to the federal requirements:

> State requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. § 360k(a)(1). Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case "parallel," rather than add to, federal requirements.

Riegel, 552 U.S. at 330 (citation omitted).

Naquin asserts that he has adequately pleaded parallel claims under *Riegel*. But parallel state law claims fail if they are pleaded in an "impermissibly conclusory and vague" fashion. *Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011). In *Funk*, we considered a pleading that, *inter alia*, alleged that "[t]he [device] contained a manufacturing defect in that it was manufactured in such a manner that impurities, residues and bacteria remained on the [device] in violation of the FDA standards and requirements and in violation of the manufacturing processes and design approved by the FDA." *Ibid.* We held that this pleading, and other similarly conclusory pleadings, did not state a parallel claim for products liability because it "d[id] not specify the manufacturing defect," did not "specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury," and did not "tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process." *Ibid.*

Naquin similarly fails to adequately plead parallel claims. He baldly asserts that the lead "was adulterated, defective, malfunctioned, and failed."

And he makes numerous conclusory allegations, such as that "[t]he FDA requires Medtronic to use conforming material in their manufacturing and Medtronic used non-conforming material." But nowhere does Naquin provide details as to how a violation of federal regulations produced a manufacturing or design defect or how a specific defect caused his alleged harms. Naquin's failure-to-warn claim is similarly conclusory, simply asserting that "[t]he Medtronic products are unreasonably dangerous because an adequate warning about the product has not been provided concerning the numerous problems, and malfunctions of these products and their component parts." Naquin's pleadings are insufficient to plead a non-preempted parallel claim. *See Funk*, 631 F.3d at 782.

Naquin also fails to adequately plead a non-preempted claim for breach of express warranty because the warranty was not alleged "with particularity" as our precedent requires. *See Wildman v. Medtronic, Inc.*, 874 F.3d 862, 870 (5th Cir. 2017). In *Wildman*, where this court found that a parallel breach-of-warranty claim was adequately pleaded and not preempted, the plaintiff's amended complaint directly quoted a two-paragraph statement from the manufacturer's website that contained the warranty allegedly relied on. *Id.* at 866. By contrast, Naquin in this case failed to reproduce any specific warranty in his pleadings or specify its precise source. Rather, Naquin stated that the lead "failed to comply with the 10 and 11 year warranty that was provided to Matthew Naquin through his physicians, and medical providers, and by Medtronic, Inc. and its employees, agents and representative, and business affiliates." The pleadings failed to identity when, where, or how Medtronic made the alleged warranty, instead listing a variety of alleged sources in conclusory fashion. This is insufficient to adequately plead a non-preempted warranty claim. *See id.* at 870; *Bass*, 669 F.3d at 515–16. In his appellate briefing, Naquin gets more specific and claims that the warranty comes from an "advertise[ment] on [Medtronic's] website," but still fails to

identify a specific web page or specific warranty terms, as the plaintiff did in *Wildman*. *See Wildman*, 874 F.3d at 866.

B.

Naquin also appeals the district court's dismissal of his breach of contract claim. But Naquin forfeited this claim by failing to replead it in the district court. "[A] failure to replead claims after being granted leave to replead constitutes [forfeiture] of any such claims on appeal." *Shakeri v. ADT Sec. Servs.*, 816 F.3d 283, 291 (5th Cir. 2016). Naquin chose not to replead and instead chose to appeal. He thus lost his contract claim.

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The judgment of the district court is AFFIRMED.